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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,314	09/05/2006	Annie Bardat	0040-0158PUS1	1865

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
07/14/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/552,314	BARDAT ET AL.	
	Examiner	Art Unit	
	YUNSOO KIM	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-17* is/are pending in the application.

4a) Of the above claim(s) *12-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-11,15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-5 and 7-17 are pending.

Claims 12-14 stand withdrawn from further consideration by the examiner 37 CFR 1.142 (b) as being drawn to a nonelected invention.

Claims 1-5, 7-11 and 15-17 are under consideration.

2. In light of Applicants' amendment filed on 4/20/09, no rejections of record remain.

3. Claim 16 is objected to because of the following informalities: "5-g/l" is noted. Appropriate correction is required.

4. The following rejections are necessitated by Applicants' amendments filed on 4/20/09.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 3-5 and 7-11 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase ", in a concentration of between 20 ppm and 50 ppm, " in line 3. Given that the commas are used before and after the concentration, it is not clear if the concentration range is referring to a sugar alcohol, glycine, or a non-ionic detergent. Appropriate correction is required.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out this invention.

8. Claims 1, 3-5 and 7-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The specification or the original claim as filed does not provide a written description for "**the formulation does not contain polyethylene glycol (PEG)**". Applicants have asserted that the support is found in p. 2 of the specification of the instant application. However, the specification discloses the general use of PEG in the protein formulation art but does not provide support for the absence of PEG in an antibody stabilizing formulation comprising a sugar alcohol, glycine and non-ionic detergent. Indeed, the indicated passage does not disclose a discussion of antibodies as the specific antigen in conjunction with PEG, nor does the cited passage discuss PEG in the presence of a sugar alcohol, glycine, and non-ionic detergent. Thus, the cited passage does not provide a nexus between PEG and antibody compositions comprising sugar alcohols, glycine and a non-ionic detergent. The specification and the original claims do not specifically indicate that antibody formulations comprising the recited sugar alcohol, glycine and non-ionic detergent are not to comprise PEG as the claims are currently amended. Therefore the instant claims now recite limitations which were not clearly disclosed in the specification as filed, and now change the scope of instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C.112.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 2 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S.Pat. No. 5,945,098 (IDS reference) as is evidenced by the MSDS for glycine, of record. Claim 2 is amended to recite "consisting essentially of" and the transitional phrase is considered open to include other components other than sugar alcohol, glycine and non-ionic detergent.

The '098 patent teaches an aqueous IgG formulation comprising mannitol, glycine and non-ionic detergents such as Tween 20 (claims 1-12, examples 1-15) and the formulation is stable.

The '098 patent further teaches that the concentration of glycine is about 0.1-0.3M, preferably about 0.2M (example 1, col. 5, lines 13-18, claim 1) and that the concentration of polysorbate is 0.002-0.004% (example 1). Given that the molecular weight of glycine is 75.07 as is evidenced by the MSDS for glycine, "about 0.1M-0.3M" is equivalent to 7g/l to 21g/l, and thus claim 17 is included. Therefore, the reference teachings anticipate the claimed invention.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-5, 7-11 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable U.S. Pat. No. 4,597,966, newly cited, in view of EP 0392,717A1, newly cited, and U.S. Pub. No. 2006/0246060A1, newly cited, as is evidenced by MSDS for mannitol and glycine, of record.

The '966 patent teaches a stabilizing IgG formulation comprising IgG, histidine and glycine at concentration of about 0.1M (claims 1-15).

The disclosure of the '966 patent differs from the instant claimed invention in that it does not teach the addition of mannitol and non-ionic detergent as is currently recited in claims 1-2 of the instant application.

The '717 publication teaches that addition of mannitol and glycine to 1:1 ratio improves stability of antibody and inhibits aggregation (claims 1-10, example 1).

As is evidenced by MSDS of mannitol and glycine, the molecular weights for mannitol and glycine are 182 and 75, respectively, the recited concentration ranges of mannitol in claims 4 and 16 and the concentration ranges of glycine in claims 5 and 17 are equivalent to 160mM-275mM and 100mM-150mM, respectively. Further, given that the term "about" is flexible and includes the concentration near 0.1M, the concentration of glycine in the '966 patent "about 0.1M" (e.g. claim14) reads on the claimed 7-10g/l of glycine. Based on the glycine concentration, the mannitol concentration in light of the '717 publication is "about 0.1M" and reads on the claimed concentration of 30g/l of claims 4 and 16 of the instant application. Therefore, claims 4, 5, 16 and 17 are included in this rejection.

The '660 publication teaches addition of 0.005% of non-ionic detergent such as polysorbate 20 improves stability by reducing aggregation ([0021]).

Given that none of the references above discloses addition of PEG, it is considered the formulation is prepared without PEG, and thus meets the limitation of the claim 1. Further claims 9-11 are included in this rejection because the combination of references results in the claimed formulation and having polymers less than 0.3% after 12 m at room temperature, or includes dimers less than 7% after 24m at 4°C as recited in claims 9-11 are expected properties of the IgG formulation comprising mannitol, glycine and non-ionic surfactant at 0.005%.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to add mannitol and non-ionic detergent as taught by the '717 publication and the '660 publication to the antibody formulation as taught by the '966 patent.

Therefore, it is prima facie obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. In re Kerkhoven, 205 USPQ 1069, CCPA 1980. See MPEP 2144.06

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the addition of mannitol and glycine improves stability of protein upon storage and delivery by reducing aggregation.

From the teachings of the references, it would have been obvious to one of ordinary skill in the art to combine teachings of the references and there would have been a reasonable expectation to success in producing the claimed invention. Therefore, the invention as a whole was a prima facie obvious to one of ordinary skill in the art at the time the invention was made as evidenced by the references, especially in the absence of evidence to the contrary.

13. No claims are allowable.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to YUNSOO KIM whose telephone number is (571)272-3176. The examiner can normally be reached on M-F, 9-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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July 08, 2009

/Michael Szperka/
Primary Examiner, Art Unit 1644